IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG, NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD. and LTS LOHMANN THERAPIE-SYSTEME AG,	:	Case No. _____
Plaintiffs,	:	
v.	:	
WATSON LABORATORIES, INC., WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC.	:	
Defendants.	:	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (hereinafter "Plaintiffs"), for their Complaint herein against defendants Watson Laboratories, Inc., Watson Pharma, Inc., and Watson Pharmaceuticals, Inc. allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharma AG ("Pharma AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Plaintiff Novartis International Pharmaceuticals Ltd. ("NIP") is a corporation organized and existing under the laws of Bermuda, having an office and place of business at Hurst Holme, 12 Trott Road, Hamilton HM LX, Bermuda.

6. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

7. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California, and another place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

8. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a

place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

9. On information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

10. On information and belief, Watson Laboratories and Watson Pharma are wholly owned subsidiaries of Watson Pharmaceuticals.

11. On information and belief, the acts of Watson Laboratories complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Watson Pharmaceuticals and Watson Pharma.

12. Defendants Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals are referred to collectively as "Watson."

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

14. On information and belief, Watson Pharmaceuticals organizes its operations by divisions—Generic, Brand, and Distribution—and reports its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. Watson Pharmaceuticals consolidates its financial results with Watson subsidiaries in its SEC filings at least for 2007 to date and does not separate financial reports to the SEC for each Watson subsidiary.

15. On information and belief, the Generic Division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals each act as agents of each other and/or work in concert with each other to further the aims of the Generic Division. On information and belief, the Generic Division, which is responsible for, *inter alia*, developing and submitting abbreviated new drug applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA"), relies on contributions from Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals.

16. On information and belief, the head of the Generic Division is an employee of Watson Pharmaceuticals, the Generic Division's ANDAs are submitted by Watson Laboratories, the Generic Division's products are manufactured also by Watson Laboratories, and the Generic Division's products are marketed and sold throughout the United States, including in Delaware, by Watson Pharma.

17. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals share a common place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

18. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals each share with the others common employees, officers, and directors.

19. On information and belief, Watson Laboratories has purposely availed itself of the rights and benefits of Delaware law and this Court. This Court previously determined in *Cephalon, Inc. v. Watson Pharmaceuticals, Inc.*, 629 F. Supp. 2d 338, 348

(D. Del. 2009), that Watson Laboratories "'regularly does or solicits business' in Delaware or engages in a 'persistent course of conduct' in Delaware."

20. On information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Laboratories is the named applicant in the FDA's Approved Drug Product List. On information and belief, Watson Pharma, acting as the agent of Watson Laboratories and Watson Pharmaceuticals, markets and sells these drugs throughout the United Stated, including in Delaware.

21. On information and belief, Watson Pharma is licensed to do business in Delaware and has sales personnel assigned to cover Delaware for the purpose of marketing and selling Generic Division products of Watson Pharmaceuticals, including Watson Laboratories' products.

22. On information and belief, Watson Laboratories and Watson Pharma are parties to one or more contractual agreements for distributing drugs manufactured under Watson Laboratories' ANDAs.

23. On information and belief, Watson Pharmaceuticals, through its own actions and the actions of one or more Watson subsidiaries, actively engages in a concerted effort to sell generic products throughout the United States, including in Delaware.

24. This Court has personal jurisdiction over defendants Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals by virtue of, *inter alia*, the above-mentioned facts. They demonstrate that Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals either directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in other persistent courses of conduct

in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals have continuous and systematic contacts in Delaware.

25. On information and belief, Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals have acted or will act as agents of each other, and/or have worked or will work in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including a rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages.

26. On information and belief, each of Watson Laboratories, Watson Pharma, and Watson Pharmaceuticals, as part of Watson Pharmaceuticals's Generic Division, would manufacture, market, and/or sell within the United States Watson's rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, if FDA approval is granted.

27. On information and belief, if approved by the FDA, Watson's rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, would be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

28. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF - PATENT INFRINGEMENT

29. Plaintiff NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6

mg/24 hr and 9.5 mg/24 hr dosages), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr) was approved by the United States Food and Drug Administration ("FDA") on July 6, 2007, and is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr) is sold in the United States by Plaintiff NPC.

30. The active ingredient in the Exelon® Patch, rivastigmine, is known chemically as (S)- 3-[1-(dimethylamino) ethyl]phenyl ethylmethylcarbamate or (S)-[N-ethyl-3[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate].

31. Plaintiff Novartis AG is the owner of United States Letters Patent No. 5,602,176 ("the '176 patent"). The '176 patent was duly and legally issued on February 11, 1997.

32. Plaintiff Novartis AG was formed as a result of the merger of Ciba-Geigy AG and Sandoz Ltd., both of Basel, Switzerland. The '176 patent was initially assigned to Sandoz Ltd. on January 29, 1988, which subsequently became Novartis AG after the merger.

33. The '176 patent claims the (S)-[N-ethyl-3-[(1-dimethylamino)ethyl]-N-methyl-phenyl-carbamate] enantiomer substantially free of its (R) isomer in free base or acid addition form, as well as pharmaceutical compositions and methods of treating conditions such as Alzheimer's disease. A true copy of the '176 patent is attached hereto as Exhibit A.

34. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

35. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the '023 patent is attached hereto as Exhibit B.

36. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 ("the '031 patent"). The '031 patent was duly and legally issued on January 1, 2002.

37. The '031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices. A true copy of the '031 patent is attached hereto as Exhibit C.

38. The '023 and '031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

39. On information and belief, Watson submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial

manufacture, use, and sale of a rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages ("Watson's ANDA Products"). On November 7, 2011, Kenton M. Walker, Esq., confirmed that the Watson entity that submitted the ANDA was defendant Watson Laboratories, a Nevada Corporation, having a place of business 311 Bonnie Circle, Corona, California. On information and belief, Mr. Walker is Senior Counsel, Intellectual Property, of defendant Watson Laboratories.

40. On information and belief, Watson submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Watson's ANDA Products before the expiration of the '176, '023, and '031 patents.

41. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Watson's ANDA Products before the expiration of the '176, '023, and '031 patents, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Products, for which Watson seeks approval in its ANDA will also infringe one or more claims of the '176, '023, and '031 patents.

42. On information and belief, Watson's ANDA Products, if approved, will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration constitutes direct infringement of the '176 patent. On information and belief, this will occur at Watson's active behest, and with Watson's intent, knowledge and encouragement. On information and belief, Watson will actively induce, encourage and abet this

administration with knowledge that it is in contravention of the rights under the ’176 patent.

43. On information and belief, Watson made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in its opinion and to the best of its knowledge, the ’176, ’023, and ’031 patents are invalid, unenforceable and/or will not be infringed.

44. On information and belief, Watson’s ANDA seeks approval to manufacture and sell Watson’s ANDA Products, which infringe the ’176, ’023, and ’031 patents.

45. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Watson’s ANDA Products, be a date that is not earlier than February 11, 2014, the expiration date of the ’176 patent, and not earlier than January 8, 2019, the expiration date of the ’023 and ’031 patents, and an award of damages for any commercial sale or use of Watson’s ANDA Products, and any act committed by Watson with respect to the subject matter claimed in the ’176, ’023, and ’031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

46. On information and belief, when Watson filed its ANDA, it was aware of the ’176, ’023, and ’031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the ’176, ’023, and ’031 patents was an act of infringement of these patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Watson has infringed one or more claims of the ’176, ’023, and ’031 patents by filing the aforesaid ANDA relating to Watson’s rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages;

B. A permanent injunction restraining and enjoining Watson and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, as claimed in the ’176, ’023, and ’031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Watson’s rivastigmine transdermal system, 4.6 mg/24 hr and 9.5 mg/24 hr dosages, be a date that is not earlier than the expiration of the right of exclusivity under the ’176, ’023, and ’031 patents;

D. Damages from Watson for the infringement of the ’176, ’023, and ’031 patents;

E. The costs and reasonable attorney fees of Plaintiffs in this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: November 9, 2011 McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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